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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/578,054	06/28/2007	Vaughn V. Smider	021216-000610US	4790
20350 7590 04/15/2011 KILPATRICK TOWNSEND & STOCKTON LLP TWO EMBARCADERO CENTER EIGHTH FLOOR SAN FRANCISCO, CA 94111-3834				
EXAMINER				
DO, PENSEE T				
ART UNIT		PAPER NUMBER		
1641				
NOTIFICATION DATE		DELIVERY MODE		
04/15/2011		ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

Docket@kilpatricktownsend.com
ipefiling@kilpatricktownsend.com
jlhice@kilpatrick.foundationip.com

Office Action Summary

Application No.

10/578,054

Applicant(s)

SMIDER ET AL.

Examiner

PENSEE DO

Art Unit

1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 February 2011.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-65 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-65 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB-08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Applicant's election with traverse of Group II, claims 16-65 in the reply filed on February 7, 2011 is acknowledged. The traversal is on the ground(s) that obviousness of combination of elements is not the standard for restriction or for lack of unity. This is found persuasive and therefore the previous restriction requirement is withdrawn.

However, a new restriction requirement is necessary as follows:

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-15, drawn to a method of detecting a target using chemiluminescent label.

Group II, claim(s) 16-29, drawn to a system comprising a chemiluminescent label bound to a non-immobilized binding pair member and an immobilized binding pair member; a solution comprising a chemical energy transferring composition that is photo reactive with the chemiluminescent label.

Group III, claim(s) 30-43, drawn to a system comprising a nucleic acid labeled with a fluorophore where the nucleic acid is in a gel and where the gel is infused with a solution comprising a chemical energy transferring composition that is photo reactive with the fluorophore.

Group IV, claim(s) 44-56, drawn to a system comprising a composition labeled with a fluorophore where the composition is bound to a solid support and where the solid support is contacted with a solution comprising an oxalic type compound and a hydroperoxide.

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Group V, claim(s) 57-65, drawn to a chemical energy transferring mixture comprising a oxalic type compound of the formula $Z(\text{CO})_2Z$ and a peroxide component and a biomolecule.

The groups of inventions listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The same or corresponding special technical features are the system of group V.

However, such features are taught by Mahant (US 5,624,813) and Crutchfield et al. (US 4,365,018).

Mahant suggests using chemiluminescent label with an oxalic ester.

"Chemiluminescence is coupled to assays by using molecules, such as luminol, acridinium esters, isoluminol, lucigenin, dioxetanes and oxalate esters, that are capable of exhibiting chemiluminescence or transferring energy to an appropriate acceptor luminescent molecule or compound. The best known chemiluminescent reactions are those of the acridinium esters, of luminol and of lucigenin. In luminol, and isoluminol, chemiluminescent reactions, the key oxidative step involves reactions of hydrogen peroxide and aminophthalhydrazide in the presence of suitable catalysts. (col. 1, lines 45-54).

Crutchfield teaches "a chemiluminescent system that is particularly advantageous to use in the present invention is an oxalate ester chemiluminescent system. This system comprises as its principal reactants the oxalate ester, an oxidizing agent, and a fluorescer. The oxidizing agent is preferably hydrogen peroxide or a precursor (e.g., a peroxo compound which will release hydrogen peroxide in the

presence of water or an acid). The chemiluminescent reaction occurs by reacting the oxalite ester with hydrogen peroxide to form a dioxetanedione in a solvent.

Dioxetanedione is very unstable and readily decomposes to carbon dioxide and releases energy. The energy released is transferred to the fluorescer which becomes electronically excited and emits light as it decays to its original ground state.” (col. 6, line 53-col. 7, line 10).

Also under PCT Rule 13.1 and 13.2 , applicants are entitled to only product. The groups II-V are drawn to different products. Therefore, Applicants are required to elect one of these products from groups II-V.

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

Group I, claim 7, please elect one species. Claims 1-6, 13-15 are generic.

Group II, claim 22, please elect one species. Claims 16-21, 28, 29 are generic.

Group III, claim 36, please elect one species. Claims 30-35, 42-43 are generic.

Group IV, claim 50, please elect one species. Claims 44-49, 56, 57 are generic.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise require all the limitations of an allowed generic claim. Currently, the following claim(s) are generic: group I, claims 1-6, 13-15 are generic; group II, claims 16-21, 28 and 29 are generic; group III, claims 30-35, 42-43 are generic; group IV, claims 44-49, 56 and 57 are generic.

REQUIREMENT FOR UNITY OF INVENTION

As provided in 37 CFR 1.475(a), a national stage application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept ("requirement of unity of invention"). Where a group of inventions is claimed in a national stage application, the requirement of unity of invention shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.

The determination whether a group of inventions is so linked as to form a single general inventive concept shall be made without regard to whether the inventions are claimed in separate claims or as alternatives within a single claim. See 37 CFR 1.475(e).

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention or species.

Should applicant traverse on the ground that the inventions have unity of invention (37 CFR 1.475(a)), applicant must provide reasons in support thereof. Applicant may submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. Where such evidence or admission is provided by applicant, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim

remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to PENSEE DO whose telephone number is (571)272-0819. The examiner can normally be reached on Monday-Friday, 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Shibuya can be reached on 571-272-0806. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Pensee T. Do/
Examiner, Art Unit 1641

***/Jacob Cheu/
Primary Examiner, Art Unit 1641***